APPARATUS AND METHOD FOR REDUCING FLUID LOSS DURING A SURGICAL PROCEDURE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present invention relates to, and is entitled to the benefit of the earlier filing date and priority of, Application No. 60/412,549, filed on September 23, 2002, and Application No. 60/415,778, filed on October 4, 2002.

FIELD OF THE INVENTION

[0002] The present invention relates to an apparatus and method for reducing fluid loss during a surgical procedure. In particular, the present invention relates to an apparatus and method for reducing blood loss from a vessel during a surgical procedure.

BACKGROUND OF THE INVENTION

[0003] An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, the aneurysm will frequently rupture, resulting in loss of blood through the rupture and death.

[0004] Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passes upward and bends over behind the heart, and passes down through the thorax and abdomen. Among other arterial vessels branching off the aorta along its path, the abdominal aorta supplies two side vessels to the kidneys, the renal

arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae (or the navel), where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

[0005] It is common for an aortic aneurysm to occur in the portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal aorta is particularly susceptible to weakening, often resulting in an aortic aneurysm. Such an aneurysm may be located near the iliac arteries. An aortic aneurysm larger than about 5 cm in diameter in this section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid, and usually fatal, hemorrhaging. Typically, a surgical procedure is not performed on aneurysms smaller than 5 cm because it has not been established that surgical intervention is beneficial for aneurysms that size.

[0006] Aneurysms in the abdominal aorta are associated with a particularly high mortality rate; accordingly, current medical standards call for urgent operative repair. Abdominal surgery, however, results in substantial stress to the body. Although the mortality rate for an aortic aneurysm is extremely high, there is also considerable mortality and morbidity associated with open surgical intervention to repair an aortic aneurysm. This intervention involves penetrating the abdominal wall to the location of the aneurysm to reinforce or replace the diseased section of the aortic aneurysm. A prosthetic device, typically a synthetic tube graft, is used for this purpose. The graft serves to exclude the aneurysm from the circulatory system, thus relieving pressure and stress on the weakened section of the aorta at the aneurysm.

[0007] Repair of an aortic aneurysm is a major operative procedure. Substantial morbidity accompanies the procedure, resulting in a protracted recovery period. Further, the procedure entails a substantial risk of mortality. While surgical intervention may be indicated, the surgery carries attendant risks and certain patients may not be able to tolerate the stress of intra-abdominal surgery. It is, therefore, desirable to reduce the mortality and morbidity associated with intra-abdominal surgical intervention.

[0008] In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intra-abdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; Lazarus, U.S. Patent No. 4,787,899 for Intraluminal Graft Device, System and Method; and Taheri, U.S. Patent No. 5,042,707 for Intravascular Stapler, and Method of Operating Same.

[0009] None of the known systems provide an apparatus that selectively reduces blood loss from a vessel during attachment of a surgical component, such as a prosthetic graft, to a vessel wall in the manner of the embodiments of the present invention. In particular, attachment devices, including, but not limited to surgical fasteners, have been developed that are intended to attach a surgical component to tissue, component to component, or tissue to tissue. An example is the attachment of a prosthetic graft to an aortic wall as described in U.S. Patent Nos. 5,944,750 and 5,957,940, which are hereby incorporated in their entirety by reference. When the attachment device is inserted independently, or in conjunction with a penetration apparatus, the attachment

device will have an opening through its center that could allow the exodus of blood from within the aortic lumen unless some sort of occlusive mechanism is built into the attachment device itself or into an additional component used in conjunction with the attachment device.

[0010] Therefore, it is an advantage of some, but not necessarily all, embodiments of the present invention to provide a device that may be added either to the attachment device or to an additional component used in conjunction with the attachment device to reduce blood loss during a surgical procedure.

[0011] Additional advantages of various embodiments of the invention are set forth, in part, in the description that follows for reducing blood loss from a vessel during a surgical procedure.

SUMMARY OF THE INVENTION

[0012] Responsive to the foregoing challenges, Applicant has developed an innovative apparatus and method for reducing blood loss from a vessel during a surgical procedure at a surgical site.

[0013] An alternative embodiment of the present invention is an occlusive system for use at a surgical site comprising a fastener and an occlusive device in cooperation with the fastener. The system may further comprise a fastener tip in communication with the fastener. The system may further comprise a penetration apparatus in communication with the fastener. The occlusive device may comprise one or more selected from the group consisting of a coil, band, ribbon, valve, and flap. In an alternative embodiment, the occlusive device may

comprise at least one of a coil, band, ribbon, valve, flap, or any other suitable element.

[0014] In an alternative embodiment, the occlusive device may have a substantially closed configuration, or a first substantially open configuration and a second substantially closed configuration. In an alternative embodiment, the occlusive device may either collapse or expand into a substantially closed configuration. In an alternative embodiment, the occlusive device may be disposed within the fastener, adjacent to the fastener, or have a first portion disposed within the fastener and a second portion extending outside the fastener.

[0015] An alternative embodiment of the present invention is an occlusive system for use at a surgical site comprising a fastener, a fastener tip in cooperation with the fastener, and an occlusive device in cooperation with the fastener or the fastener tip. The occlusive device may be in cooperation with the fastener, the fastener tip, or both.

[0016] An alternative embodiment of the present invention is an occlusive system for use at a surgical site comprising a fastener, an occlusive device in cooperation with the fastener, and a penetration apparatus in reversible communication with the fastener and the occlusive device. The occlusive device may have a first substantially open configuration and a second substantially closed configuration.

[0017] An alternative embodiment of the present invention is an occlusive system for use at a surgical site comprising fastener means for fastening a first component to a second component, and occlusive means in cooperation with

the fastener means for reducing fluid flow at the surgical site. The first component and second component may be comprised of a surgical component, a tissue, or both.

[0018] An alternative embodiment of the present invention is a method for reducing the loss of fluid at a surgical site comprising the steps of advancing an occlusive system comprising a fastener having an occlusive device to a surgical site and deploying the surgical fastener having the occlusive device at the surgical site. The method may further comprise the step of reducing the loss of fluid at the surgical site. The fluid may be blood, or any blood component.

[0019] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] In order to assist the understanding of this invention, reference will now be made to the appended drawings, in which like reference characters refer to like elements.

[0021] Figure 1 A and B is a schematic view of an occlusive system in accordance with an embodiment of the present invention.

[0022] Figure 2A is a cut-away pictorial view of an occlusive system including a penetration apparatus, fastener, occlusive device (not shown), and a fastener tip according to an embodiment of the present invention.

[0023] Figure 2B is a perspective view of a fastener tip according to an embodiment of the present invention.

[0024] Figure 3 is a cut-away pictorial view of the insertion of the penetration apparatus and the fastener through the surgical component and the vessel wall in accordance with an embodiment of the present invention.

[0025] Figure 4 is a cut-away pictorial view of the fastener deployed through the surgical component and the vessel in accordance with an embodiment of the present invention.

[0026] Figures 5 and 6 are schematic views of an occlusive system according to an embodiment of the present invention.

[0027] Figure 7A and B is a schematic view of an occlusive system according to an embodiment of the present invention.

[0028] Figure 8A, B, C, D, E, and F is a perspective view of an occlusive device according to an embodiment of the present invention.

[0029] Figure 9 is a cross-sectional view of an occlusive system according to an embodiment of the present invention having an opened flap valve.

[0030] Figure 10 is a cross-sectional view of the embodiment of Fig. 9 with the flap valve in a closed configuration.

[0031] Figure 11A and B is a schematic view of an example embodiment of the device comprising a thin wall material.

[0032] Figure 12A and B is a schematic view of another example embodiment of the device comprising a thin wall material.

[0033] Figures 13, 14, and 15 are perspective views of further example embodiments of the device directed to a valve.

[0034] Figure 16A and B is a schematic view of an embodiment of the device directed to the tapered tip.

[0035] Figure 17A, B, and C is a schematic view of an embodiment of the device directed to a thin wall material.

[0036] Figure 18A, B, and C is a schematic view of an example embodiment of the device directed to a polymeric cord.

[0037] Figures 19A and B and 20A, B, and C are schematic views of further embodiments of the occlusive device directed to an expandable material.

[0038] Figures 21 and 22 are cut-away pictorial views of further embodiments of the occlusive device directed to a mass of shape memory material in an opened and a closed configuration.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0039] Reference will now be made in detail to various embodiments of the present invention, examples of which are illustrated in the accompanying drawings. As shown in Fig. 1, occlusive system **10** in accordance with an embodiment of the present invention comprises occlusive device **50** in communication with surgical fastener **30**. Occlusive device **50** may be disposed within, or located adjacent to surgical fastener **30**. Occlusive device **50** may comprise, but is not limited to, one or more coils, bands, ribbons, valves, flaps or any other suitable occlusive member. Occlusive device **50** may be static, expanding, and/or collapsing. In an alternative embodiment, occlusive device **50** may remain in a first substantially closed position, or may have a first substantially closed position and a second substantially open position. In an embodiment having a first and second position, occlusive device **50** is biased toward the first substantially closed position.

[0040] In alternative embodiments, occlusive system **10** comprises occlusive device **50** and surgical fastener **30** alone, or occlusive device **50** and surgical fastener **30** in combination with surgical fastener tip **40**, and/or penetration apparatus **20**, or any combination of the above. Various embodiments are discussed in greater detail in the following paragraphs.

[0041] In an alternative embodiment, occlusive system **10** comprises occlusive device **50**, surgical fastener **30**, and surgical fastener tip **40**. Surgical fastener tip **40** is located adjacent to surgical fastener **30**. Occlusive device **50** may be disposed within and/or located adjacent to fastener **30**, or disposed within and/or located adjacent to surgical fastener tip **40**, as shown in Fig. 5.

[0042] In an alternative embodiment, occlusive system **10** may comprise occlusive device **50**, surgical fastener **30**, and penetration apparatus **20**. Penetration apparatus **20** may comprise an optical fiber or any other apparatus to penetrate the surgical site including, but not limited to, a screw, a drill, a needle, or any other suitable mechanical or thermal energy means. Various embodiments of penetration apparatus **20** are described in U.S. Patent Nos. 5,972,023; 5,957,940; 6,371,919; 5,997,556; 6,248,118; 6,520,974; 6,607,555, all of which are incorporated in their entirety by reference. When penetration apparatus **20** is used in conjunction with occlusive system **10**, occlusive device **50** is maintained in the second substantially open position by the presence of penetration apparatus **20**. Upon withdrawal of penetration apparatus **20** during the surgical procedure, occlusive device **50** assumes its first substantially closed position thereby reducing the loss of fluid at the surgical site. The fluid may be,

but is not limited to, blood, blood products, and blood components. The surgical site may be within a lumen, such as, but not limited to a vessel.

[0043] Occlusive system **10** in accordance with an alternative embodiment of the present invention is described in connection with Figs. 2 through 4. In this embodiment, occlusive system **10** comprises fastener **30**, occlusive device **50**, tip **40**, and penetration apparatus **20**. Occlusive system **10** reduces blood loss when fastener **30** spans a surgical site. At the surgical site, occlusive system **10** advances through a lumen, such as, but not limited to, a vessel (not shown) that may have surgical component **100** adjacent to vessel wall **200**, as shown in Fig. 2. In an example embodiment illustrated in Fig. 2, surgical component **100** and vessel wall **200** are shown with inside or interluminal potion **200A** and outside or adventitial portion **200B**. The surgical site, however, is not limited to a surgical component and a vessel but may be any combination of the surgical component and/or the vessel, such as, but not limited to, a surgical component to a surgical component, a surgical component to a vessel, or a vessel to a vessel.

[0044] In Fig. 2, fastener **30** is a flexible fastener that applies a force to attach surgical component **100** to the vessel wall **200**, as disclosed in the following U.S. Patents and Patent Applications: U.S. Provisional Patent Application No. 60/181,230, filed February 9, 2000; U.S. Patent Application No. 09/442,768, filed November 18, 1999; U.S. Patent Application No. 09/213,233, filed December 17, 1998, now U.S. Patent No. 5,997,556; U.S. Patent Application No. 08/958,524, filed October 27, 1997, now U.S. Patent No. 5,957,940; U.S. Patent Application No. 08/896,415, filed July 18, 1997, now U.S. Patent No.

5,944,750; and U.S. Provisional Patent Application No. 60/051,209, filed June 30, 1997. The subject matter of these patents and patent applications is incorporated herein in its entirety specifically by reference. In further example embodiments, fastener **30** may or may not apply a compressive force to attach surgical component **100** to vessel wall **200**.

[0045] In an alternative embodiment shown in Fig. 2A, fastener **30** is disposed about or around penetration apparatus **20**. Fastener **30** may be disposed about, around, proximal or distal to the surgical site, or within penetration apparatus **20**. In further example embodiments, fastener **30** may be linked to penetration apparatus **20** in a manner such that the insertion of penetration apparatus **20** at the surgical site also includes the insertion of fastener **30**, as illustrated in Fig. 3. Fastener **30** may be inserted at the surgical site before, concurrently with, or after, penetration apparatus **20**. Fastener **30** may be sectioned into leading portion **32**, middle portion **34**, and trailing portion **36**. Each portion of fastener **30** may be similar or different in structure and may be composed of similar or different materials such as, but not limited to, plastic, metal, metal alloy, or any other suitable material.

[0046] In the embodiment illustrated in Fig. 2A, fastener **30** is reversibly or irreversibly secured to tip **40**. Tip **40** may facilitate penetration of the surgical site and in further embodiments, includes occlusive device **50** for reducing blood loss at the surgical site, as shown in Fig. 5. In one embodiment, tip **40** is attached to leading portion **32** of fastener **30**, but also may be located elsewhere on fastener **30**, such as, but not limited to, middle portion **34** and/or trailing

portion **36**. As shown in Figure 2B, tip **40** may include inner lumen **42**, leading edge **44**, middle portion **46**, and trailing edge **48**. Tip **40** may facilitate penetration with or without the use of penetration apparatus **20**, and may be composed of any suitable material, such as, but not limited to, plastic, metal, or metal alloy. Tip **40** shown in Figs. 2A and 2B is of a conical or a bell shape, but may be of any suitable shape.

[0047] In further alternative embodiments of occlusive system **10**, occlusive device **50** is housed within fastener **30** itself, located in one or more of leading portion **32**, middle portion **34**, or trailing portion **36**, or into an apparatus attached to fastener **30**, such as, but not limited to, tip **40**. When penetration apparatus **20** is engaged with fastener **30** as depicted in Fig. 2A, occlusive device **50** assumes a second substantially open configuration. When penetration apparatus **20** is removed as shown in Fig. 4, occlusive device **50** assumes its first substantially closed configuration.

[0048] Various alternative embodiments of occlusive device **50** of occlusive system **10** will now be described with reference to Figs. 1 and 6 through 22. In example embodiments illustrated in Fig. 1, occlusive device **50** comprises a spring winding or coil member that may be tapered and attached to fastener **30** and/or tip **40**. Occlusive device **50** may be attached to fastener **30** in various ways such as, but not limited to, extension of the fastener wires, welded, threaded over the fastener, or any other suitable method of attachment. When penetration apparatus **20** is engaged with fastener **30** in Fig 1A, occlusive device **50** is in a second substantially open configuration. When penetration apparatus

20 is removed, occlusive device **50** retracts toward fastener **30** into a first substantially closed configuration, as shown in Fig. 1B. This retraction of occlusive device **50** assists in the reduction of fluid loss during and following the surgical procedure. Various embodiments of occlusive device **50** may be disposed at leading portion **32**, middle portion **34**, or trailing portion **36** of fastener **30** and/or with an apparatus, such as, but not limited to, tip **40**. Illustrated in Figs. 5 and 6, occlusive device **50** is located within tip **40**.

[0049] An alternative embodiment illustrated in Figs. 7A and 7B shows occlusive device **50** disposed in trailing portion **36** of fastener **30**. In particular, occlusive device **50** is comprised of a spring or spiral coil which may be fabricated from a solid disk. In Figs. 7A and 7B, fastener **30** is also attached to tip **40** opposite occlusive device **50**. When fastener **30** encompasses penetration apparatus **20**, as in Fig. 7A, occlusive device **50** assumes a second substantially open configuration. When penetration apparatus **20** is withdrawn, as shown in Fig. 7B, occlusive device **50** assumes its first substantially closed configuration or retracted shape and provides resistance to fluid and/or blood flow. Occlusive device **50**, according to this embodiment, may be fabricated from a metal, a polymeric material or any other suitable material and may be attached to fastener **30** in a number of ways, including, but not limited to, material specific welding, or any other suitable bonding techniques.

[0050] The alternative embodiments of occlusive device **50** shown in Figs. 8A and 8B comprise a solid tapering cylinder with flap segments **52** that may be cut in a longitudinal manner and biased in a first substantially closed position.

When penetration apparatus **20** is inserted through occlusive device **50**, flap segments **52** may be distracted into a second substantially open position and when penetration apparatus **20** is withdrawn from occlusive device **50**, flap segments **52** return to their first substantially closed position. In additional embodiments, occlusive device **50** is disposed within or attached to fastener **30** or into another structure such as, but not limited to, tip **40**. Figs. 8B through 8F depict further, non-limiting embodiments of occlusive device **50** with sagittal cuts there through. In particular, Fig. 8B is a straight cone; Fig. 8C is an insloping cone; Fig. 8D is an outsloping cone; Fig. 8E is a hemisphere; and Fig. 8F is an abbreviated hourglass.

[0051] In the alternative embodiments of the present invention depicted in Figs. 9 and 10, occlusive device **50** comprises a flap valve from a sagittal cut through tip **40** that may be attached to leading portion **32** of fastener **30**. In Fig. 9, penetration apparatus **20** distracts occlusive device **50** such as those depicted in Figs. 8A through 8F. In Fig. 10, penetration apparatus **20** is removed allowing occlusive device **50** to return to its first substantially closed position within tip **40**.

[0052] Another alternative embodiment of occlusive device **50** is shown in Figs. 11 and 12. Occlusive device **50** comprises a thin wall material attached to tip **40**, leading portion **32**, middle portion **34**, and/or trailing portion **36** of fastener **30** or at any other suitable location. The thin wall material of occlusive device **50** may comprise a thin wall tube, polymeric, biodegradable polymer or any other suitable material. In Figs. 11A and 11B, occlusive device **50** may be preformed

over trailing portion **36** of fastener **30**. In Fig. 11A, a portion of penetration apparatus **20** is disposed within fastener **30** such that occlusive device **50** encircles penetration apparatus **20**. In Fig. 11B, penetration apparatus **20** is withdrawn and occlusive device **50** collapses into its first substantially closed position assisting in the reduction of fluid and/or blood flow through fastener **30**.

[0053] In a further alternative embodiment, occlusive device **50** illustrated in Figs. 12A and 12B attaches to tip **40**. The thin wall material comprising occlusive device **50** is preformed over trailing edge **48** of tip **40**. Similarly, the thin wall material may be composed of thin wall tube, polymeric, biodegradable or any other suitable material. In Fig. 12A, penetration apparatus **20** extends through fastener **30** and is encircled by occlusive device **50**. In Fig. 12B, the removal of penetration apparatus **20** collapses occlusive device **50** into its first substantially closed configuration resembling a "duck-bill" thereby reducing fluid and/or blood flow through fastener **30**.

[0054] In Figs. 13 through 15, additional alternative embodiments directed to occlusive device **50** are shown. In these figures, occlusive device **50** comprises a valve. Occlusive device **50** may be located within fastener **30** or within a separate apparatus to be attached to fastener **30**, such as, but not limited to, tip **40**. Occlusive device **50** may be constructed of metal alloys, synthetic material with or without elastomeric properties, or any other suitable materials. Occlusive device **50** of Fig. 13 is in a "duck-bill" configuration. In Fig. 14, occlusive device **50** is a tricuspid valve configuration having at least one cusp. Alternatively, in Fig. 15, occlusive device **50** is a radially expansive aperture valve. When

penetration apparatus **20** inserts through occlusive device **50** illustrated in Figs. 13 through 15, occlusive device **50** distracts or opens and when penetration apparatus **20** is removed, occlusive device **50** assumes its first substantially closed configuration. Occlusive device **50** depicted in Figs. 13 through 15 is illustrated in the first substantially closed configuration.

[0055] A further alternative embodiment of occlusive device **50** is illustrated in Figs. 16A and 16B. Occlusive device **50** is integrated with tip **40** to form a unitary structure. In Figs. 16A and 16B, occlusive device **50** comprises a circular cone having multiple webs that may be equispaced and/or identical. The embodiment of Figs. 16A and 16B depicts tip **40** shaped in a cone having three webs. In alternative embodiments, tip **40** is threaded, crimped, shrunk or associated with leading portion **32** of fastener **30** or via any other suitable means. In Fig. 16A, penetration apparatus **20** is positioned within fastener **30** and distends occlusive device **50** of tip **40**. As shown in Fig. 16B, penetration apparatus **20** is withdrawn resulting in a collapse of occlusive device **50** to its first substantially closed position to reduce fluid and/or blood flow through the fastener **30**.

[0056] According to another alternative embodiment illustrated in Figs. 17A and 17B, occlusive device **50** is comprised of a thin wall material that may be shrunk over leading portion **32** or trailing portion **36** of fastener **30**. Occlusive device **50** may be secured to fastener **30** by crimping, screwing, shrink-wrapping, heating, welding, or attachment by any other suitable means. In example embodiments depicted in Fig. 17A, occlusive device **50** may be

polymeric tubing shrunk over leading portion **32** of fastener **30**. Illustrated in Fig. 17B, the cross section shows occlusive device **50** in a second substantially open configuration with penetration apparatus **20** in position within fastener **30**. Fig. 17C depicts occlusive device **50** in its first substantially closed configuration after removal of penetration apparatus **20** from the surgical site.

[0057] Further alternative embodiments of the invention are shown in Figs. 18A and 18B. Occlusive device **50** may comprise a polymeric coil, ribbon, or cord positioned intermittently between and among a plurality of coils of fastener **30**. Illustrated in Fig. 18A, occlusive device **50** is disposed in middle portion **34** of fastener **30** and around penetration apparatus **20**, although occlusive device **50** may be disposed in leading portion **32** or trailing portion **36** of fastener **30**. In Fig. 18B, separation **56** of occlusive device **50** is shown with fastener **30** and penetration apparatus **20**. Occlusive device **50** is also in a second substantially open configuration in the presence of penetration apparatus **20**. In contrast, Fig. 18C illustrates occlusive device **50** in its first substantially closed configuration with removal of penetration apparatus **20**.

[0058] Various alternative embodiments of the present invention are also illustrated in Figs. 19A and 19B. Occlusive device **50** may comprise one or more expandable members comprised of a polymeric foam or elastomer, or any other suitable expandable component. In an alternative embodiment, occlusive device **50** is located in tip **40** where it is compressed in the presence of penetration apparatus **20** into its second substantially open position, as shown in Fig. 19A. When penetration apparatus **20** is removed, as shown in Fig. 19B,

occlusive device **50** may assume its first substantially closed position within tip **40** thereby reducing fluid and/or blood flow through fastener **30**.

[0059] In other alternative embodiments, tip **40** may be composed of expandable material or biodegradable material (not shown). In this instance, fastener **30** is aligned over penetration apparatus **20** and over a reduced diameter of tip **40**. With the removal of penetration apparatus **20**, tip **40** may enlarge thereby forming a barrier to reduce the flow of fluid and/or blood through fastener **30**.

[0060] As illustrated in Figs. 20A, 20B and 20C, the expandable material of occlusive device **50** comprises an expandable plug. In various embodiments, occlusive device **50** is comprised of a polymeric or electrometric foam or any other suitable expandable component. Occlusive device **50**, as illustrated in Fig. 20A and 20B, is positioned in a slot within tip **40**. Tip **40** may be attached to fastener **30**. With penetration apparatus **20** in place, as shown in Fig. 20B, occlusive device **50** is compressed and held in its second substantially open position. With the removal of penetration apparatus **20** from the surgical site, as depicted in Fig. 20C, occlusive device **50** may expand to its first substantially closed position, thereby assisting in the reduction of fluid and/or blood flow through fastener **30**.

[0061] Example alternative embodiments illustrated in Figs. 21 and 22 are directed to occlusive device **50** comprising a mass of shaped memory material. Occlusive device **50** may be comprised of coils, ribbon, and/or wire or any other suitable material disposed within tip **40** or any other appropriate location within

tip **40** or fastener **30**. In Fig. 21, occlusive device **50** is in a deformed second substantially open configuration allowing penetration apparatus **20** to pass through fastener **30**. In Fig. 22 with the removal of penetration apparatus **20** from the surgical site, occlusive device **50** assumes its first substantially closed or pre-formed configuration thereby inhibiting the flow of fluid and/or blood through fastener **30**. Occlusive device **50** may also possess thrombic properties to inhibit the blood flow. Occlusive device **50** may assume a configuration of such a size that it would not be able to move through fastener **30** or tip **40**.

[0062] An embodiment of the method of operating occlusive system **10** will now be described. Occlusive system **10** comprising fastener **30** and occlusive device **50** is advanced to a surgical site through a lumen, such as, but not limited to, a vessel as disclosed in the following U.S. Patents and Patent Applications: U.S. Provisional Patent Application No. 60/181,230, filed February 9, 2000; U.S. Patent Application No. 09/442,768, filed November 18, 1999; U.S. Patent Application No. 09/213,233, filed December 17, 1998, now U.S. Patent No. 5,997,556; U.S. Patent Application No. 08/958,524, filed October 27, 1997, now U.S. Patent No. 5,957,940; U.S. Patent Application No. 08/896,415, filed July 18, 1997, now U.S. Patent No. 5,944,750; and U.S. Provisional Patent Application No. 60/051,209, filed June 30, 1997, incorporated in their entirety specifically by reference. Occlusive system **10** is deployed at the surgical site attaching surgical component **100** to vessel wall **200**, or surgical component to surgical component, or vessel to vessel, or any combination of the above. Occlusive device **50** in its first substantially closed position reduces blood loss

through fastener **30** during and following the surgical procedure.

[0063] In an alternative embodiment shown in Fig. 2A, occlusive system **10** is advanced to the surgical site through a lumen, such as, but not limited to, a vessel (not shown). Penetration apparatus **20** is advanced either simultaneously or in sequence with tip **40** of fastener **30** to contact surgical component **100**. Penetration apparatus **20** positioned with fastener **30** engages occlusive device **50** resulting in a second substantially open configuration. Penetration apparatus **20** and/or tip **40** creates an aperture within surgical component **100** and vessel wall **200**. As indicated in Fig. 3, penetration apparatus **20** extends through surgical component **100** and vessel wall **200** such that fastener **30** also extends through surgical component **100** and vessel wall **200**. In Fig. 4, penetration apparatus **20** is withdrawn from within fastener **30**. Leading portion **32** of fastener **30** attached to tip **40** and trailing portion **36** resume their preformed coiled coil shape while middle portion **34** extends through surgical component **100** and vessel wall **200**. With the withdrawal of penetration apparatus **20**, occlusive device **50** assumes its first substantially closed configuration thereby reducing the flow of blood from adventitial portion **200B** to luminal portion **200A** and/or vice versa (not shown). Occlusive system **10** may be deployed at the surgical site as described in U.S. Patent Nos. 5,972,023; 5,957,940; 6,371,919; 5,997,556; 6,248,118; 6,520,974; 6,607,555, and U.S. Patent Application No. 10/417,163, filed April 17, 2003, herein incorporated in their entirety by reference. Occlusive system **10** may be advanced to the surgical site and deployed without the use of a penetration apparatus **20**, or without the use of a

surgical tip **40**. Various embodiments of occlusive system **10** may be used to attach one or more of a surgical component, such as, but not limited to a prosthetic graft, and a tissue, such as, but not limited to a vessel. In one example embodiment occlusive system **10** comprising occlusive device **50** and surgical fastener **30** is deployed during the surgical procedure to attach a surgical component to a vessel, a surgical component to another surgical component, a vessel to vessel, or any combination thereof.

[0064] Numerous characteristics and advantages have been set forth in the foregoing description, together with details of structure and function. The novel features are pointed out in the appended claims. The disclosure, however, is illustrative only, and changes may be made in detail, especially in matters of shape, size and arrangement of parts, within the principle of the invention, to the full extent indicated by the broad general meaning of the terms in which the appended claims are expressed.